K003719

FEB 2 8 2001

APPENDIX A 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____

Applicant Information:

Date Prepared: December 1, 2000

Name: Vascular Architects, Inc.
Address: 1830 Bering Drive
San Jose, CA 95112

Contact Person: Jean Caillouette
Phone Number: (408) 392-7437
Fax Number: (408) 453-7970

Device Information:

Trade Name: Vascular Architects **PERISCOPE™ Device**

Common Name: Intraluminal Artery Stripper

Classification Name: Intraluminal Artery Stripper

Equivalent (Predicate) Devices:

K950813: Vascular Architects MollRing Cutter®

Intended Use:

The Vascular Architects Vessel Dissector is intended for remote intraluminal stripping of peripheral blood vessels during vascular reconstruction and to provide a conduit for guidewire placement.

General indications for peripheral reconstruction include disabling claudication, ischemic pain at rest, or ischemic skin lesions or gangrene. Indications for endarterectomy specifically as a procedure for vessel reconstruction include localized lesions and heavy circumferential plaque deposits.

Comparison To Predicate Devices:

This device has the same intended use and technological characteristics as the predicate device. Device materials are similar to the MollRing Cutter.

Non-clinical Test Results:

Bench testing was conducted comparing the Vascular Architects **PERISCOPE Device** to the predicate device and device performance was found to be equivalent. Additional testing was performed to ensure that the mechanical integrity and performance are in accordance with the established design specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2001

Ms. Jean M. Cailloutte
Manager, Regulatory Affairs
Vascular Architects, Inc.
1830 Bering Dr.
San Jose, CA 95112-4226

Re: K003719
Trade Name: Vascular Architects Periscope Device
Regulatory Class: II (two)
Product Code: 74 DWX
Dated: December 1, 2000
Received: December 4, 2000

Dear Ms. Cailloutte:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K003719

Device Name: Vascular Architects **PERISCOPE™ Device**

Indications for Use: The Vascular Architects **PERISCOPE™ Device** is intended for remote intraluminal stripping of peripheral blood vessels during vascular reconstruction and to provide a conduit for guidewire placement.

General indications for peripheral reconstruction include disabling claudication, ischemic pain at rest, ischemic skin lesions or gangrene. Indications for endarterectomy specifically as a procedure for vessel reconstruction include localized lesions and heavy circumferential plaque deposits.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

(Optimal Format 1-2-96)

2/22/1

Division of Cardiovascular & Respiratory Devices
510(k) Number K003719

Confidential